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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,612	08/13/2001	Pierre Golstein	015631-003115US	9875

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EXAMINER
HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
1637	12

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/929,612	GOLSTEIN ET AL.	
	Examiner	Art Unit	
	Kenneth R Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 23-45* is/are pending in the application.

4a) Of the above claim(s) *42-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 23-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 . (2 pages)
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Applicant's election with traverse of Group III, claims 1-2 and 23-41, SEQ ID NO:5 and 7, in Paper No. 11 is acknowledged. The traversal is on the ground(s) that no serious burden would exist to examine the claims of Groups III and IV together. An appendix is attached showing significant areas of sequence identity between SEQ ID NO:9 and 5/7. This is not found persuasive because SEQ ID NO:9 represents a mouse sequence while the elected SEQ ID NO:5/7 represents a human sequence, and although there is significant sequence homology significant differences exist as well, requiring separate analysis of sequence searching results which would indeed be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 42-45, and the embodiments of claims 1-2 and 23-41 covering SEQ ID NO:1, 3, and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The current claims are drawn to nucleic acids.

5. Claims 1, 23, 24, 26-28, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1 and 23 are confusing because it cannot be determined what sequences other than the elected SEQ ID NO:5 and 7 encode a "CTLA protein".

B) Claim 1 is further confusing as containing reference to non-elected subject matter, SEQ ID NO:1, 3, and 9.

C) Regarding claim 23, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

D) Claim 24 is confusing because it cannot be determined what is encompassed by "stringent conditions". The specification provides only examples of what might be considered as such conditions, rather than providing a definition.

E) Claims 26 and 27 are confusing as containing reference to non-elected subject matter, SEQ ID NO:2, 4, 6, and 10.

F) Claim 28 is confusing because "the coding sequence" lacks proper antecedent basis.

G) Claim 39 is confusing because of the language "does not replicate (autonomously)", as it is unclear how the parenthetical affects the claim scope.

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24 and 26-28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter (product of nature). The claimed subject matter reads on native mRNA or genomic sequences corresponding to SEQ ID NO:5/7. Amending the claims such that they are drawn to isolated nucleic acids would obviate this rejection.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 23-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to generic nucleic acids, and the proper inquiry regarding written description is: (1) have a representative number of species been described by complete structure, and if not, (2) have a representative number of species been described by sufficient relevant identifying characteristics. It is submitted that these criteria are not satisfied in the instant case. Regarding claims 1, 2, 23, and 24, besides failing to describe any and every "mammalian" CTLA –encoding nucleic acid, the specification fails to describe which of the enormous number of "fragments" (including nucleotides and small n-mers) of such a nucleic acid have any use as specific probes, for example. Regarding claim 24, the specification clearly does not describe any and every nucleic acid which hybridizes under the specified conditions to SEQ ID NO:5 or 7, some of which might not have any functional similarity whatsoever with these sequences. Similar analysis applies to claim 25, which covers any and every nucleic acid which might be isolated using a probe of SEQ ID NO:5 or 7. This rejection also applies to claims 26-41, because although independent claims 26 and 27 include a percent identity limitation,

the claimed nucleic acids lack any functional requirement which would exclude nucleic acids of related sequence but having no similar function. Further, with respect to claim 28, the specification fails to describe any genomic sequences containing introns.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by the 1992 Gibco BRL catalog.

Due to the "fragment thereof" embodiment, these claims are broad enough to read on single nucleotides, which may be interpreted as "fragments" of the claimed nucleic acids. On page 299 of the above catalog, single nucleotides are taught.

9. The nucleic acids of SEQ ID NO:5 and 7, and nucleic acids encoding the polypeptide of SEQ ID NO:8, are considered allowable subject matter. Claims 25-41 are free of the prior art, but are rejected for other reasons. No claims are allowable. Jacobs et al. (US 6,043,344) and Yao et al. (US 5,869,286) are made of record by the examiner, as these disclose nucleic acids and polypeptides with some sequence similarity to instant SEQ ID NO:5, 7, and 8.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kenneth R. Horlick, Ph.D.

Kenneth R Horlick
Primary Examiner
Art Unit 1637

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June 9, 2003